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| IDS Form PTO/SB/08: Substitute for form 1449/PTO<br>DEC 28 2004                               |   |    |   | <b>Complete if Known</b> |                     |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br>(Use as many sheets as necessary) |   |    |   | Application Number       | 10/721,022          |
|   |   |    |   | Filing Date              | November 25, 2003   |
|   |   |    |   | First Named Inventor     | Lukas-Laskey et al. |
|   |   |    |   | Art Unit                 | 1614                |
|   |   |    |   | Examiner Name            | Not Yet Assigned    |
| Sheet   | 1 | of | 1 | Attorney Docket Number   | 04012.0384-00000    |

| U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS |                       |  |   |   |   |
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| Examiner Initials                                   | Cite No. <sup>1</sup> | Document Number                          | Issue or Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|   |                       | Number-Kind Code <sup>2</sup> (if known) |   |   |   |
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| FOREIGN PATENT DOCUMENTS |                       |   |                                |   |   |                          |
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|                          |                       | Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known) |                                |   |   |                          |
| PS                       |                       | CA 1,259,071  | 09-05-1989                     | BOEHRINGER MANNHEIM GMBH                        |   |                          |
| PS                       |                       | EP 0 808 162 B1   | 11-26-1997                     | BOEHRINGER MANNHEIM PHARM CORP (US)             |   |                          |
| PS                       |                       | DE 696 02 424 T2  | 11-26-1997                     | BOEHRINGER MANNHEIM PHARM CORP (US)             |   | Yes                      |
|                          |                       |   |                                |   |   |                          |

| NON PATENT LITERATURE DOCUMENTS |                       |   |                          |
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| Examiner Initials               | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | Translation <sup>6</sup> |
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Sheet 1 of 24

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|    | 83. | Notice of Application, Hoffmann-La Roche Ltd and Smithkline Beecham Corp. v. Minister of Health and Novopharm Ltd., Court No. T-84-02, Federal Court, Trial Division (Canada) (Jan. 16, 2002) .            |  |
|    | 84. | Pharmascience, Notice of Allegation regarding carvedilol, 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg (August 30, 2001) .  |  |
|    | 85. | Notice of Application, GlaxoSmithKline Inc. and SmithKline Beecham Corp. v. Minister of Health and Pharmascience Inc., Court No. T-1871-01, Federal Court, Trial Division (Canada) (October 18, 2001) .    |  |
|    | 86. | Reasons for Order and Order, GlaxoSmithKline Inc. and SmithKline Beecham Corp. v. Minister of Health and Pharmascience Inc., Court No. T-1871-01, Federal Court, Trial Division (Canada) (July 18, 2003) . |  |
|    | 87. | Apotex Inc., Notice of Allegation in respect to Canadian Letters Patent No. 2,212,548 (June 19, 2003) .  |  |
|    | 88. | Swedberg, K., et al., "Beneficial effects of long-term beta-blockade in congestive cardiomyopathy," <i>Brit Heart J.</i> , 44, 117-33 (1980) .   |  |
|    | 89. | Swedberg, K., et al., "Adverse effects of beta-blockade withdrawal in patients with congestive cardiomyopathy," <i>Brit. Heart J.</i> , 44, 134-42 (1980) .  |  |
|    | 90. | Drexler, H. et al., "Characterization of skeletal muscle $\beta$ -adrenergic receptors in patients with chronic heart failure, <i>Circulation</i> 80(4), II-116 (1989) .                                   |  |
| ✓  | 91. | Diehm, C., Antihypertensive therapy in arterial occlusive disease, <i>Vasa Suppl</i> , 33, 71-4 (1991) (English language abstract only) .  |  |

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| Examiner Signature | P. Spivack | Date Considered | 7/5/05 |
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|  |   |    |    | First Named Inventor     | Lukas-Laskey et al. |
|  |   |    |    | Art Unit                 | 1614                |
|  |   |    |    | Examiner Name            | Not Yet Assigned    |
| Sheet  | 7 | of | 24 | Attorney Docket Number   | 04012.0384-00000    |

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| PS | 92.  | Sponer, G., et al., "Pharmacological profile of $\beta$ -adrenoceptor blockers with vasodilating properties, especially Carvedilol - rationale for clinical use," Clin. Investig., 70, S20-S26 (1992).  |  |
|    | 93.  | Lessem, J.N., Weber, M.A., "Antihypertensive treatment with a dual-acting beta-blocker in the elderly," J. Hypertens Suppl., 11(4), S29-36 (1993) (Abstract only).  |  |
|    | 94.  | Olsen, S.L., et al., " $\beta$ -Blocker related improvement in submaximal exercise tolerance in heart failure from idiopathic dilated cardiomyopathy (IDC)," JACC, 19, 146A, Abstract 747-5 (March 1, 1992).                                      |  |
|    | 95.  | Harder S., et al., "Lack of pharmacokinetic interaction between carvedilol and digitoxin or phenprocoumon," Eur. J. Clin. Pharmacol, 44(6), 583-6 (1993) (Abstract only).   |  |
|    | 96.  | Bristow, M.R., et al., "The $\beta$ -blocking agents metoprolol and Carvedilol affect cardiac adrenergic drive differently in subjects with heart failure from idiopathic dilated cardiomyopathy," JACC, 21(2), 314A (Feb. 1993) (Abstract only). |  |
| ✓  | 97.  | Australia/New Zealand Heart Failure Research Collaborative Group, "Randomised, placebo-controlled trial of Carvedilol in patients with congestive heart failure due to ischaemic heart disease," Lancet, 349, 375-80 (Feb. 8, 1997).              |  |
|    | 98.  | Teva, Patent Certification Notice Letter re U.S. Patent Nos. 5,760,069 and 5,902,821 (May 24, 2002)   |  |
| PS | 99.  | Packer, M., "Effect of Carvedilol on Survival in Severe Chronic Heart Failure," New England J. Med., 344(22), 1651-1658 (May 31, 2001).   |  |
|    | 100. | Judgment, German Federal Republic Judgment nullity action 3 Ni 44/00 relating to DE 696 02 424 (EP 0 808 162), Egis Gyogyszergyar RT v. F. Hoffmann-La Roche AG (September 18, 2001) (English language translation)                               |  |
|    | 101. | Defendant's Answer to Summons of July 6, 2001, German Federal Republic nullity action 3 Ni 44/00 relating to DE 696 02 424 (EP 0 808 162), Egis Gyogyszergyar RT v. Hoffmann-La Roche AG (August 23, 2001) (English language translation)         |  |
|    | 102. | Plaintiff's Brief, German Federal Republic nullity action 3 Ni 44/00 relating to DE 696 02 424 (EP 0 808 162), Egis Gyogyszergyar RT v. Boehringer Hoffmann-La Roche AG (August 7, 2001) (English language translation)                           |  |

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|   |   |    |    | First Named Inventor     | Lukas-Laskey et al. |
|   |   |    |    | Art Unit                 | 1614                |
|   |   |    |    | Examiner Name            | Not Yet Assigned    |
| Sheet   | 8 | of | 24 | Attorney Docket Number   | 04012.0384-00000    |

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|  | 103. | Substantiation of Opposition of Sept. 21, 2000, German Federal Republic nullity action 3 Ni 44/00 relating to DE 696 02 424 (EP 0 808 162), Egis Gyogyszergyar RT v. Boehringer Hoffmann-La Roche AG (Dec. 8, 2000) (English language translation)   |  |
|  | 104. | Nullification Petition, German Federal Republic nullity action relating to DE 696 02 424 (EP 0 808 162), Egis Gyogyszergyar RT v. Boehringer Hoffmann-La Roche AG (August 4, 2000) (English language translation)  |  |
|  | 105. | Judgment, German Federal Republic Judgment nullity action 3 Ni 57/91 relating to DE 36 12 537 (October 27, 1992) (English language translation)  |  |
|  | 106. | Ruling, German Federal Republic, Federal Patent Court, concerning Patent 22 23 237 (Jan. 13, 1989) (English Language Translation)  |  |
|  | 107. | Official Action, German Patent Office, Application No. P. 195 03 995.5-41 (August 17, 1995).   |  |
|  | 108. | Official Action, German Patent Office, Application No. P. 195 03 995.5-41 (November 7, 1995).  |  |
|  | 109. | Affidavit of Dr. William T. Abraham (March 8, 2002), filed in Hoffmann-La Roche Ltd and Smithkline Beecham Corp. v. Minister of Health and Novopharm Ltd., Court No. T-84-02, Federal Court, Trial Division (Canada), further including:<br><u>Exhibit A</u> : Curriculum Vitae of Dr. William T. Abraham,<br><u>Exhibit B</u> : Novopharm, Notice of Allegation and Detailed Statement- Carvedilol 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg Tablets (Nov. 28, 2001),<br><u>Exhibit C</u> : Canadian Patent Number 2,212,548,<br><u>Exhibit D</u> : Glossary of Terms, and<br><u>Exhibit E</u> : Commentary of Remaining Prior Art in Appendices A & B of the Novopharm Notice of Allegation. |  |
|  | 110. | Affidavit of Dr. Mark Lautens (March 8, 2002), filed in Hoffmann-La Roche Ltd and Smithkline Beecham Corp. v. Minister of Health and Novopharm Ltd., Court No. T-84-02, Federal Court, Trial Division (Canada), further including:<br><u>Exhibit A</u> : Curriculum Vitae of Dr. Mark Lautens,<br><u>Exhibit B</u> : Novopharm, Notice of Allegation and Detailed Statement- Carvedilol 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg Tablets (Nov. 28, 2001), and<br><u>Exhibit C</u> : Canadian Patent Number 1,259,071.   |  |

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|   |   |    |    | First Named Inventor     | Lukas-Laskey et al. |
|   |   |    |    | Art Unit                 | 1614                |
|   |   |    |    | Examiner Name            | Not Yet Assigned    |
| Sheet   | 9 | of | 24 | Attorney Docket Number   | 04012.0384-00000    |

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| 111. | <p>Affidavit of Edwin J. Gale (March 8, 2002), filed in Hoffmann-La Roche Ltd and Smithkline Beecham Corp. v. Minister of Health and Novopharm Ltd., Court No. T-84-02, Federal Court, Trial Division (Canada), further including:</p> <p><u>Exhibit A</u>: Canadian Patent Number 2,212,548,</p> <p><u>Exhibit B</u>: Novopharm, Notice of Allegation and Detailed Statement- Carvedilol 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg Tablets (Nov. 28, 2001),</p> <p><u>Exhibit C</u>: Chart of Claim Types and Allowability in Canada,</p> <p><u>Exhibit D</u>: Notice concerning acceptable claim types, Canadian Patent Office Record (May 9, 1989),</p> <p><u>Exhibit E</u>: Canadian Patent Office Manual of Patent Office Practice, §§ 11.10 - 11.10.02 (March 1998), and</p> <p><u>Exhibit F</u>: Chart of Claims of Canadian Patent Number 2,212,548, with claims grouped by type.</p> |  |
| 112. | <p>Affidavit of Dr. Nadia S. Giannetti (March 8, 2002), filed in Hoffmann-La Roche Ltd and Smithkline Beecham Corp. v. Minister of Health and Novopharm Ltd., Court No. T-84-02, Federal Court, Trial Division (Canada), further including:</p> <p><u>Exhibit 1</u>: Curriculum Vitae of Dr. Nadia S. Giannetti,</p> <p><u>Exhibit 2</u>: Novopharm, Notice of Allegation and Detailed Statement- Carvedilol 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg Tablets (Nov. 28, 2001),</p> <p><u>Exhibit 3</u>: Canadian Patent Number 2,212,548,</p> <p><u>Exhibit 4</u>: Chart of Articles and Patents,</p> <p><u>Exhibit 5</u>: Letter of February 18, 2002, from Nika V. Ketis, Ph.D., LL.B. (Heenan Blaikie LLP) to Judith Robinson (Ogilvy Renault) regarding Case T-84-02.</p>  |  |

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|  |    |    |    | <i>First Named Inventor</i>   | Lukas-Laskey et al. |
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| Sheet  | 10 | of | 24 |                               |                     |

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| 113. |  | <p>Affidavit of Dr. John Parker (March 11, 2002), filed in Hoffmann-La Roche Ltd. and Smithkline Beecham Corp. v. Minister of Health and Novopharm Ltd., Court No. T-84-02, Federal Court, Trial Division (Canada), further including:</p> <p><u>Exhibit A</u>: Curriculum Vitae of Dr. John Parker,</p> <p><u>Exhibit B</u>: Novopharm, Notice of Allegation and Detailed Statement- Carvedilol 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg Tablets (Nov. 28, 2001),</p> <p><u>Exhibit C</u>: Canadian Patent Number 2,212,548,</p> <p><u>Exhibit D</u>: Glossary of Terms,</p> <p><u>Exhibit E</u>: Packer, M., et al., "The Effect of Carvedilol on Morbidity and Mortality in Patients with Chronic Heart Failure," New England J. Med. 334(21), 1349-1355 (May 23, 1996),</p> <p><u>Exhibit F</u>: Waagstein, F., "Beneficial Effects of Metoprolol in Idiopathic Dilated Cardiomyopathy," Lancet, 342, 1441-1446 (Dec. 11, 1993),</p> <p><u>Exhibit G</u>: CIBIS Investigators and Committees, "A Randomized Trial of <math>\beta</math>-Blockade in Heart Failure," Circulation, 90(4), 1765-1773 (Oct. 1994),</p> <p><u>Exhibit H</u>: Pfeffer, M.A., et al., "<math>\beta</math>-Adrenergic Blockers and Survival in Heart Failure," New England J. Med. 334(21), 1396-97 (May 23, 1996),</p> <p><u>Exhibit I</u>: Packer, M., "Effect of Carvedilol on Survival in Severe Chronic Heart Failure," New England J. Med., 344(22), 1651-1658 (May 31, 2001),</p> <p><u>Exhibit J</u>: Beta-Blocker Evaluation of Survival Trial Investigators, "A Trial of the Beta-Blocker Bucindolol in Patients with Advanced Chronic Heart Failure," New England J. Med. 344(22), 1659-1667 (May 31, 2001), and</p> <p><u>Exhibit K</u>: Commentary on Remaining Prior Art in Appendices A &amp; B of the Novopharm Notice of Allegation.</p> |  |
| 114. |  | <p>Affidavit of Dr. Ian Winterborn (March 11, 2002), filed in Hoffmann-La Roche Ltd and Smithkline Beecham Corp. v. Minister of Health and Novopharm Ltd., Court No. T-84-02, Federal Court, Trial Division (Canada), further including</p> <p><u>Exhibit A</u>: Curriculum Vitae for Dr. Ian Winterborn,</p> <p><u>Exhibit B</u>: Novopharm, Notice of Allegation and Detailed Statement- Carvedilol 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg Tablets (Nov. 28, 2001),</p> <p><u>Exhibit C</u>: Notice of Application, Hoffmann-La Roche Ltd and Smithkline Beecham Corp. v. Minister of Health and Novopharm Ltd., Court No. T-84-02, Federal Court, Trial Division (Canada) (Jan. 16, 2002),</p> <p><u>Exhibit D</u>: Canadian Patent Number 2,212,548,</p> <p><u>Exhibit E</u>: Canadian Patent Number 1,259,071,</p> <p><u>Exhibit F</u>: Canadian Patent Number 1,129,416, and</p> <p><u>Exhibit G</u>: United States Patent Number: 4,503,067.</p>   |  |

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| 115. | <p>Affidavit of Dr. Mary Ann Lukas (March 7, 2002), filed in Hoffmann-La Roche Ltd and Smithkline Beecham Corp. v. Minister of Health and Novopharm Ltd., Court No. T-84-02, Federal Court, Trial Division (Canada), further including:</p> <p><u>Exhibit A</u>: Curriculum Vitae for Dr. Mary Ann Lukas,</p> <p><u>Exhibit B</u>: Canadian Patent Number 2,212,548,</p> <p><u>Exhibit C</u>: German Patent Application No. 195 03 995.5 (PCT/EP 96/00498),</p> <p><u>Exhibit D</u>: English Translation of German Patent Application No. 195 03 995.5 (PCT/EP 96/00498),</p> <p><u>Exhibit E</u>: U.S. Patent Application Number 08/483,635,</p> <p><u>Exhibit F</u>: Novopharm, Notice of Allegation and Detailed Statement- Carvedilol 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg Tablets (Nov. 28, 2001),</p> <p><u>Exhibit G</u>: Loeg, H.S., et al., "Effect of Enalapril, Hyralazine Plus Isosorbide Dinitrate, and Prazonsin on Hospitalization in Patients with Chronic Congestive Heart Failure," Circulation 87(6), VI78 - VI87 (June 1993),</p> <p><u>Exhibit H</u>: DiBianco, R., et al., "A Comparison of Oral Milrinone, Digoxin, and Their Combination in the Treatment of Patients with Chronic Heart Failure," New England J. Med., 320(11), 677-683 (March 1989)</p> <p><u>Exhibit I</u>: Packer, M., et al., "Effect of Oral Milrinone on Mortality in Severe Chronic Heart Failure," New England J. Med. 325(21), 1468-75 (Nov. 21, 1991),</p> <p><u>Exhibit J</u>: Feldman, A.M., et al., "Effects of Vesnarinone on Morbidity and Mortality in Patients with Heart Failure," New England J. Med., 329(3), 149-155 (July 15, 1993)</p> <p><u>Exhibit K</u>: Kamoterol in severe heart failure study group, "Xamoterol in Severe Heart Failure," Lancet, 336, 1-6 (July 7, 1990),</p> <p><u>Exhibit L</u>: Waagstein, F., et al., "Beneficial Effects of Metoprolol in Idiopathic Dilated Cardiomyopathy," Lancet 342, 1441-1446 (Dec. 11, 1993),</p> <p><u>Exhibit M</u>: CIBIS Investigators and Committees, "A Randomized Trial of <math>\beta</math>-Blockade in Heart Failure," Circulation, 90(4), 1765-1773 (Oct. 1994),</p> <p><u>Exhibit N</u>: Packer, M., et al., "The Effect of Carvedilol on Morbidity and Mortality in Patients with Chronic Heart Failure," New England J. Med. 334(21), 1349-1355 (May 23, 1996),</p> <p><u>Exhibit O</u>: Pfeffer, M.A., et al., "<math>\beta</math>-Adrenergic Blockers and Survival in Heart Failure," New England J. Med. 334(21), 1396-97 (May 23, 1996),</p> <p><u>Exhibit P</u>: Packer, M., "Effect of Carvedilol on Survival in Severe Chronic Heart Failure," New England J. Med., 344(22), 1651-1658 (May 31, 2002), and</p> <p><u>Exhibit Q</u>: Commentary on Remaining Prior Art in Appendices A and B of the Novopharm Notice of Allegation.</p> |  |
| 116. | <p>Respondent's Record (Pharmascience Inc.) Volume I of III filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health, and Pharmascience Inc., Court File No. T-1871-01 (Canada), containing an index and:</p> <p><u>Exhibit A</u>: Exhibits to cross-examination of Dr. William T. Abraham taken on June 4, 2002. "77<sup>th</sup> Cardiovascular and Renal Drugs Advisory Committee meeting dated May 2, 1996," pp. 1-356.</p>  |  |

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| 117. | Respondent's Record (Pharmascience Inc.) Volume II of III filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court File No. T-1871-01 (Canada), containing an Index and:<br><u>Continuation of Exhibit A</u> to Dr. William T. Abraham's cross-examination (pp. 357-572)<br><u>Exhibit B</u> : Exhibits to cross-examination of Dr. Nadia S. Giannetti taken on June 21, 2002. "Study regarding sauna induced myocardial ischemia in patients with coronary artery disease," pp. 573-578.<br><u>Exhibit C</u> : Exhibits to cross-examination of Dr. Mary Ann Lukas taken on July 12, 2002. 1) Precise Trial Documentation, pp. 579-752 and 2) CPS Coreg Reference, pp. 753-756. |  |
| 118. | Respondent's Record (Pharmascience Inc.) Volume III of III filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court File No. T-1871-01 (Canada), containing an index and:<br><u>Exhibit D</u> : Memorandum of Fact and Law, pp. 757-802. Appendix A ("Anticipation by Kelly") to Respondent's Memorandum of Fact and Law, pp. 788-801.   |  |

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| 119. | <p>Applicants' Record Volume 1 of 6 filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court No. T-1871-00 (Canada), containing an Index and:</p> <p><u>Exhibit A</u>: Pharmascience Inc. Notice of Allegation dated August 30, 2001, pp. 1-11;</p> <p><u>Exhibit B</u>: Notice of Application issued October 18, 2001 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 12-27;</p> <p><u>Exhibit C</u>: Pharmascience Inc. Notice of Appearance dated October 26, 2001 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 28-31;</p> <p><u>Exhibit D</u>: Order of Prothonotary Lafrenière dated December 13, 2001 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 32-35;</p> <p><u>Exhibit E</u>: Order of Prothonotary Lafrenière dated March 7, 2002 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 36-39;</p> <p><u>Exhibit F</u>: Order of Prothonotary Lafrenière dated June 11, 2002 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 40-44;</p> <p><u>Exhibit G</u>: Confidentiality Order of Prothonotary Lafrenière dated August 2, 2002 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 45-55;</p> <p><u>Exhibit H</u>: Affidavit of Dr. William T. Abraham sworn January 29, 2002 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 56-96, further including: <u>Exhibit A</u>: Curriculum vitae, pp. 97-142; <u>Exhibit B</u>: Notice of Allegation, pp. 143-154; <u>Exhibit C</u>: Canadian Letters Patent No. 2,212,548, pp. 155-186; <u>Exhibit D</u>: Glossary of medical terms, pp. 187-193; <u>Exhibit E</u>: Further commentary on prior art, pp. 194-209;</p> <p><u>Exhibit I</u>: Transcript of cross-examination of Dr. Abraham taken on June 4, 2002 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 210-350, further including Exhibit 1 (Vogel et al., 24 Am. J. Cardiology 198-207 (1969)), Exhibit 2 (Bristow et al., 94 Circulation 2807-2816 (1996)), Exhibit 3 (Gilbert et al., 94 Circulation 2817-2825 (1996)), and Exhibit 4 (Shakar et al., 31 JACC 1336-1340 (1998));</p> <p><u>Exhibit J</u>: Affidavit of Dr. Nadia S. Giannetti sworn January 30, 2002 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 351-371, further including: Exhibit 1: Curriculum vitae, pp. 372-384; Exhibit 2: Notice of Allegation, pp. 385-396; Exhibit 3: Canadian Letters Patent No. 2,212,548, pp. 397-428; Exhibit 4: List of prior art referenced in Notice of Allegation, pp. 429-438;</p> <p><u>Exhibit K</u>: Transcript of cross-examination of Dr. Giannetti taken on June 21, 2002 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 439-529.</p> |
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|   |    |    |    | Application Number       | 10/721,022          |
|   |    |    |    | Filing Date              | November 25, 2003   |
|   |    |    |    | First Named Inventor     | Lukas-Laskey et al. |
|   |    |    |    | Art Unit                 | 1614                |
|   |    |    |    | Examiner Name            | Not Yet Assigned    |
| Sheet   | 14 | of | 24 | Attorney Docket Number   | 04012.0384-00000    |

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| 120. | Applicants' Record Volume 2 of 6 filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court No. T-1871-00 (Canada), containing an Index and:<br><u>Exhibit L</u> : Affidavit of Patricia N. Jansons sworn January 24, 2002 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 530-540, further including: <u>Exhibit A</u> : Certified copy of Canadian Letters Patent No. 1,259,071, pp. 541-583; <u>Exhibit B</u> : Certified copy of the Abstract of Title for Canadian Letters Patent No. 1,259,071, pp. 584-585; <u>Exhibit C</u> : Certified copy of Canadian Letters Patent No. 2,212,548, pp. 586-617; <u>Exhibit D</u> : Certified copy of the Abstract of Title for Canadian Letters Patent No. 2,212,548, pp. 618-619; <u>Exhibit E</u> : Copy of CPS entry for COREG™, pp. 620-625; <u>Exhibit F</u> : Copies of the 76 prior art references listed as paragraphs 1 to 13 and Appendix A of the Notice of Allegation (Tabs 1-46), pp. 626-1022.   |  |
| 121. | Applicants' Record Volume 3 of 6 filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court No. T-1871-00 (Canada), containing an Index and:<br><u>Exhibit L</u> (cont.): <u>Exhibit F</u> : Copies of the 76 prior art references listed at paragraphs 1 to 13 and Appendix A of the Notice of Allegation (Tabs 47-76), pp. 1023-1186;<br><u>Exhibit M</u> : Affidavit of Dr. Mary Ann Lukas sworn January 30, 2002 (Canada, Federal Court-Trial Division, Court No. 1871-01), pp. 1187-1212, further including: <u>Exhibit A</u> : Curriculum vitae, pp. 1214-1221, <u>Exhibit B</u> : Canadian Letters Patent No. 2,212,548, pp. 1222-1253; <u>Exhibit C</u> : German Patent Application No. 19503995.5 dated February 8, 1995, pp. 1254-1260; <u>Exhibit D</u> : English translation of German Application, pp. 1261-1267; <u>Exhibit E</u> : U.S. Patent Application No. 08/483,635 dated June 7, 1995, pp. 1268-1290; <u>Exhibit F</u> : Notice of Allegation, pp. 1291-1302; <u>Exhibit G</u> : Loeb publication, 1993, pp. 1303-1313; <u>Exhibit H</u> : DiBianco publication, 1989, pp. 1314-1321; <u>Exhibit I</u> : Packer publication, 1991, pp. 1322-1330; <u>Exhibit J</u> : Feldman publication, 1993, pp. 1331-1338; <u>Exhibit K</u> : Results of Xamoterol Trial, pp. 1339-1345; <u>Exhibit L</u> : Results of Metoprolol in Dilated Cardiomyopathy (MDC) Trial, pp. 1346-1352; <u>Exhibit M</u> : Results of the CIBIS I Trial, pp. 1353-1362; <u>Exhibit N</u> : Results of the U.S. Carvedilol Trials, pp. 1363-1370; <u>Exhibit O</u> : Pfeffer editorial on U.S. Carvedilol Trials, pp. 1371-1373; <u>Exhibit P</u> : Results of COPERNICUS Trial, pp. 1374-1382; <u>Exhibit Q</u> : Further commentary on prior art, pp. 1383-1393. |  |

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|   |    |    |    | Application Number       | 10/721,022          |
|   |    |    |    | Filing Date              | November 25, 2003   |
|   |    |    |    | First Named Inventor     | Lukas-Laskey et al. |
|   |    |    |    | Art Unit                 | 1614                |
|   |    |    |    | Examiner Name            | Not Yet Assigned    |
| Sheet   | 15 | of | 24 | Attorney Docket Number   | 04012.0384-00000    |

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| 122. | <p>Applicants' Record Volume 4 of 6 filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court No. T-1871-00 (Canada), containing an Index and:</p> <p><u>Exhibit N</u>: Transcript of cross-examination of Dr. Lukas taken on July 12, 2002 (Canada, Federal Court-Trial Division, Court No. T-1871-01), pp. 1394-1795, further including Exhibit 1 (SmithKline Beecham Pharm., SK&amp;F 105517/Carvedilol, protocol 220 (October 20, 1993), Exhibit 2 (SmithKline Beecham Pharm., SK&amp;F 105517/Carvedilol, protocol 221 (October 20, 1993)), Exhibit 3 (SmithKline Beecham Pharm., SK&amp;F 105517/Carvedilol, protocol 239 (June 9, 1994)), Exhibit 4 (SmithKline Beecham Pharm., SK&amp;F 105517/Carvedilol, protocol 240 (January 25, 1994));</p> <p><u>Exhibit O</u>: Affidavit of Dr. John Parker sworn January 31, 2002 (Canada, Federal Court-Trial Division, Court No. T-1871-01), pp. 1796-1828, further including: <u>Exhibit A</u>: Curriculum vitae, pp. 1829-1851; <u>Exhibit B</u>: Notice of Allegation, pp. 1852-1863; <u>Exhibit C</u>: Canadian Letters Patent No. 2,212,548, pp. 1864-1896; <u>Exhibit D</u>: Glossary of medical terms, pp. 1897-1903; <u>Exhibit E</u>: Results of U.S. Carvedilol Trials, pp. 1904-1910; <u>Exhibit F</u>: Results of Metoprolol in Dilated Cardiomyopathy (MDS) Trials, pp. 1911-1917; <u>Exhibit G</u>: Results of CIBIS I Trial, pp. 1918-1927; <u>Exhibit H</u>: Pfeffer editorial on U.S. Carvedilol Trials, pp. 1928-1930; <u>Exhibit I</u>: Results of COPERNICUS Trial, pp. 1931-1939; <u>Exhibit J</u>: Results of BEST Trial, pp. 1940-1949; <u>Exhibit K</u>: Further commentary on prior art, pp. 1950-1959;</p> <p><u>Exhibit P</u>: Transcript of cross-examination of Dr. Parker taken on July 3, 2002, pp. 1960-2082..</p> |
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|   |    |    |    | Application Number       | 10/721,022          |
|   |    |    |    | Filing Date              | November 25, 2003   |
|   |    |    |    | First Named Inventor     | Lukas-Laskey et al. |
|   |    |    |    | Art Unit                 | 1614                |
|   |    |    |    | Examiner Name            | Not Yet Assigned    |
|   |    |    |    | Attorney Docket Number   | 04012.0384-00000    |
| Sheet   | 16 | of | 24 |                          |                     |

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| 123. | <p>Applicants' Record Volume 5 of 6 filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court No. T-1871-00, containing an Index and:</p> <p><u>Exhibit Q</u>: Affidavit of Dr. Bertram Pitt sworn April 1, 2002 (Canada, Federal Court-Trial Division, Court No. T-1871-01), pp. 2083-2121, further including <u>Exhibit A: Curriculum vitae</u>, pp. 2122-2193; <u>Exhibit B</u>: Comparison document prepared by Hitchman &amp; Sprigings, pp. 2194-2209;</p> <p><u>Exhibit R</u>: Transcript of cross-examination of Dr. Pitt taken on June 24, 2002 (Canada, Federal Court-Trial Division, Court No. T-1871-01), pp. 2210-2284;</p> <p><u>Exhibit S</u>: Affidavit of Dr. Robert Rangno sworn April 1, 2002 (Canada, Federal Court-Trial Division, Court No. T-1871-01), pp. 2285-2324, further including <u>Exhibit 1: Curriculum vitae</u>, pp. 2325-2342; Exhibits 2-4 not included: Documents struck by Canadian Court order dated June 11, 2002</p> <p><u>Exhibit T</u>: Transcript of cross-examination of Dr. Rangno taken on June 26, 2002 (Canada, Federal Court-Trial Division, Court No. T-1871-01), pp. 2346-2411;</p> <p><u>Exhibit U</u>: Affidavit of Patrick Taylor sworn April 2, 2002 (Canada, Federal Court-Trial Division, Court No. T-1871-01), pp. 2412-2414, further including: <u>Exhibit A</u>: Product Monograph for COREG™ (carvedilol), pp. 2415-2419; <u>Exhibit B</u>: Further Detailed Information of the Prior Art References found in Appendix "A" to the Pharmascience Notice of Allegation, pp. 2420-2463; Exhibits C-F not included: Documents struck by Canadian Court order dated June 11, 2002;</p> <p><u>Exhibit V</u>: Affidavit of Dr. Lawrence Zisman sworn April 1, 2002 (Canada, Federal Court-Trial Division, Court No. T-1871-01), pp. 2469-2490, further including: <u>Exhibit A: Curriculum vitae</u>, pp. 2491-2504; <u>Exhibit B</u>: Comparison document prepared by Hitchman &amp; Sprigings, pp. 2505-2521;</p> <p><u>Exhibit W</u>: Transcript of cross-examination of Dr. Zisman taken on July 10, 2002, pp. 2522-2592.</p> |  |
| 124. | <p>Applicants' Record Volume 6 of 6 filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court No. T-1871-00, further including:</p> <p><u>Exhibit X</u>: Written Representations, Applicants' Memorandum of Fact and Law, pp. 2593-2623.</p>   |  |

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|   |    |    |    | Application Number       | 10721,022           |
|   |    |    |    | Filing Date              | November 25, 2003   |
|   |    |    |    | First Named Inventor     | Lukas-Laskey et al. |
|   |    |    |    | Art Unit                 | 1614                |
|   |    |    |    | Examiner Name            | Not Yet Assigned    |
| Sheet   | 17 | of | 24 | Attorney Docket Number   | 04012.0384-00000    |

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|  | 125. | Affidavit of Edwin J. Gale, March 8, 2002, filed in Hoffmann-La Roche Limited, and Smithkline Beecham Corporation v. The Minister of Health, and Novopharm Limited, Court No. T-84-02, further including:<br><u>Exhibit A</u> : Copy of Canadian Letters Patent No. 2,212,548;<br><u>Exhibit B</u> : Notice of Allegation dated November 28, 2001 from Novapharm Limited to Hoffmann-La Roche;<br><u>Exhibit C</u> : Chart of Edwin J. Gale illustrating various claim types used to cover pharmaceuticals including first and second medical uses and pharmaceuticals;<br><u>Exhibit D</u> : Practice Notice regarding Chemical Patent Practice from the Canadian Patent Office Record of May 9, 1989;<br><u>Exhibit E</u> : Copy of section on Method of Use and Use claims from the Canadian Manual of Patent Office Practice dated March 1998;<br><u>Exhibit F</u> : Copy of Canadian Patent No. 2,212,548 claims grouped by type. |  |
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|  |    |    |    | Application Number       | 10/721,022          |
|  |    |    |    | Filing Date              | November 25, 2003   |
|  |    |    |    | First Named Inventor     | Lukas-Laskey et al. |
|  |    |    |    | Art Unit                 | 1614                |
|  |    |    |    | Examiner Name            | Not Yet Assigned    |
| Sheet  | 18 | of | 24 | Attorney Docket Number   | 04012.0384-00000    |

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| 126. | <p>Applicants' Record filed in GlaxoSmithKline Inc. and Smithkline Beecham Corporation v. Apotex Inc. and The Minister of Health, Court File No. T-2105-02 (Canadian Federal Court-Trial Division), containing an Index and:</p> <p><u>Exhibit A</u>: Apotex Inc. Notice of Allegation dated November 1, 2003, pp. 1-2;<br/> <u>Exhibit B</u>: Notice of Application dated December 16, 2002, pp. 3-13;<br/> <u>Exhibit C</u>: Apotex Inc. Notice of Appearance dated December 20, 2002, pp. 14-16;<br/> <u>Exhibit D</u>: Minister of Health Notice of Appearance dated December 31, 2002, pp. 17-18;<br/> <u>Exhibit E</u>: Affidavit of Lidia O. Derewlany sworn on February 14, 2003, pp. 19-23, further including: Exhibit 1: Canadian Patent No. 2,212,548, pp. 24-54; Exhibit 2: Abstract of title for Canadian Patent No. 2,212,548, pp. 55-56; Exhibit 3: German Patent Application No. 19503995.5, pp. 57-63; Exhibit 4: English translation of German Patent Application No. 19503995.5, pp. 64-70; Exhibit 5: U.S. Patent Application No. 08/483,635, pp. 71-92; Exhibit 6: Notice of Compliance dated February 17, 1995 and approved product monograph for Kredex tablets, pp. 93-115; Exhibit 7: Cover page of the S/NDS dated December 13, 1995 for Coreg<sup>TM</sup> tablets (redacted), pp. 116-118; Exhibit 8: Correspondence from Viera Pastorek, Health Canada, dated January 10, 1996, pp. 119-121; Exhibit 9: Notice of Compliance dated September 30, 1996, pp. 122-160; Exhibit 10: Health Canada Patent Lists filed by Hoffmann-LaRoche for Coreg<sup>TM</sup> tablets, pp. 161-165; Exhibit 11: Cover page for the September 13, 2001 S/NDS filed by GlaxoSmithKline Inc., pp. 166-167; Exhibit 12: Correspondence from A. Minkiewicz-Janda dated October 29, 2001, pp. 168-171; Exhibit 13: Health Canada Patent Lists filed by GlaxoSmithKline Inc., pp. 172-176; Exhibit 14: Notice of Compliance dated April 10, 2002 and approved product monograph for Coreg<sup>TM</sup> tablets, pp. 177-227;<br/> <u>Exhibit F</u>: Transcript of cross-examination of Lidia O. Derewlany taken April 24, 2003, pp. 229-269;<br/> <u>Exhibit G</u>: Correspondence dated May 23, 2003 for Ogilvy Renault to Goodmans LLP, pp. 270-271;<br/> <u>Exhibit H</u>: Affidavit of Dianne Kathleen Grisé sworn on February 14, 2003, pp. 272-275;<br/> <u>Exhibit I</u>: Transcript of cross-examination of Dianne Kathleen Grisé taken May 6, 2003, pp. 276-312;<br/> <u>Exhibit J</u>: Affidavit of Bernard Sherman sworn on March 7, 2003, pp. 313-315;<br/> <u>Exhibit K</u>: Written Representations, memorandum of Fact and Law, of GlaxoSmithKline and SmithKline Beecham Corporation dated June 5, 2003, pp. 316-346.</p> |
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|  |    |    |    | <i>Filing Date</i>            | November 25, 2003   |
|  |    |    |    | <i>First Named Inventor</i>   | Lukas-Laskey et al. |
|  |    |    |    | <i>Art Unit</i>               | 1614                |
|  |    |    |    | <i>Examiner Name</i>          | Not Yet Assigned    |
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| 127. | <p>Applicants' Record, Volume 1 of 7, filed in Hoffmann-La Roche Limited and Smithkline Beecham Corporation v. The Minister of Health and Novopharm Limited, Court No. T-84-02 (Canadian Federal Court-Trial Division), containing an Index and:</p> <p><u>Exhibit A</u>: Novopharm Limited Notice of Allegation dated November 28, 2001, pp. 1-20;</p> <p><u>Exhibit B</u>: Notice of Application issued January 16, 2002, pp. 21-36;</p> <p><u>Exhibit C</u>: Novopharm Limited Notice of Appearance dated January 18, 2002, pp. 37-39;</p> <p><u>Exhibit D</u>: Minister of Health Notice of Appearance dated January 24, 2002, pp. 40-41;</p> <p><u>Exhibit E</u>: Order of Prothonotary Lafrenière dated February 11, 2002, pp. 42-44;</p> <p><u>Exhibit F</u>: Confidentiality Order of Prothonotary Lafrenière dated February 11, 2002, pp. 45-52;</p> <p><u>Exhibit G</u>: Correspondence dated February 18, 2002 from Heenan Blaikie, counsel for the Respondent, Novopharm Limited to Ogilvy Renault, counsel for the Applicants, pp. 53-55;</p> <p><u>Exhibit H</u>: Order of Prothonotary Lafrenière dated November 4, 2002, pp. 56-57;</p> <p><u>Exhibit I</u>: Correspondence dated January 27, 2003 from Heenan Blaikie, counsel for the Respondent, Novopharm Limited to Ogilvy Renault, counsel for the Applicants, pp. 53-57a;</p> <p><u>Exhibit J</u>: Affidavit of Patricia N. Jansons sworn March 4, 2002, pp. 58-72, further including: <u>Exhibit A</u>: Certified copy of Canadian Letters Patent No. 1,259,071, pp. 73-115; <u>Exhibit B</u>: Certified copy of the Abstract of Title for Canadian Letters Patent No. 1,259,071, pp. 116-117; <u>Exhibit C</u>: Certified copy of Canadian Letters Patent No. 2,212,548, pp. 118-146; <u>Exhibit D</u>: Certified copy of the Abstract of Title for Canadian Letters Patent No. 2,212,548, pp. 147-148; <u>Exhibit E</u>: Copy of CPS entry for COREG™, pp. 149-154; <u>Exhibit F</u>: Copies of the 104 prior art references listed at page 5 &amp; 6 and Appendix A &amp; B of the Novopharm Notice of Allegation, pp. 155-534.</p> |
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|   |    |    |    | <i>Filing Date</i>            | November 25, 2003   |
|   |    |    |    | <i>First Named Inventor</i>   | Lukas-Laskey et al. |
|   |    |    |    | <i>Art Unit</i>               | 1614                |
|   |    |    |    | <i>Examiner Name</i>          | Not Yet Assigned    |
| Sheet   | 20 | of | 24 | <i>Attorney Docket Number</i> | 04012.0384-00000    |

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| 128. | <p>Applicants' Record, Volume 3 of 7, filed in Hoffmann-La Roche Limited, and Smithkline Beecham Corporation v. The Minister of Health and Novopharm Limited, Court No. T-84-02, further including:</p> <p><u>Exhibit K</u>: Affidavit of Dr. Mary Ann Lukas sworn March 7, 2002, pp. 1026-1059, further including: <u>Exhibit A</u>: Curriculum vitae, pp. 1060-1067; <u>Exhibit B</u>: Canadian Letters Patent No. 2,212,548, pp. 1068-1105; <u>Exhibit C</u>: German Patent Application No. 19503995.5 dated February 8, 1995, pp. 1106-1112; <u>Exhibit D</u>: English translation of German Application, pp. 1113-1119; <u>Exhibit E</u>: U.S. Patent Application No. 08/483,635 dated June 7, 1995, pp. 1120-1141; <u>Exhibit F</u>: Novopharm Notice of Allegation (Nov. 28, 2001), pp. 1142-1162; <u>Exhibit G</u>: Loeb et al., 87 Circulation VI-78 to VI-87 (1993), pp. 1163-1173; <u>Exhibit H</u>: DiBianco et al., 320 N.E.J. Med. 677-683 (1989), pp. 1174-1181; <u>Exhibit I</u>: Packer et al., 325 N.E.J. Med. 1468-1475 (1991), pp. 1182-1190; <u>Exhibit J</u>: Feldman et al., 329 N.E.J. Med. 149-155 (1993), 1191-1198; <u>Exhibit K</u>: Results of Xamoterol Trial, 336 Lancet 1-6 (1990), pp. 1199-1205; <u>Exhibit L</u>: Results of the Metoprolol in Dilated Cardiomyopathy (MDS) Trial, 342 Lancet 1441-46 (1993), pp. 1206-1212; <u>Exhibit M</u>: Results of the CIBISA Trial, 90 Circulation 1765-1773 (1994), pp. 1213-1222; <u>Exhibit N</u>: Results of the U.S. Carvedilol Trials, 334 N.E.J. Med. 1349-1355, pp. 1223-1230; <u>Exhibit O</u>: Pfeffer editorial on U.S. Carvedilol Trials 334 N.E.J. Med. 1396-1397, pp. 1231-1233; <u>Exhibit P</u>: Results of COPERNICUS Trial, 344 N.E.J. Med. 1651-1658, pp. 1234-1242; <u>Exhibit Q</u>: Further commentary on prior art, pp. 1243-1256; <u>Exhibit L</u>: Transcript of cross-examination of Dr. Lukas taken on January 28, 2003, pp. 1257-1333;</p> <p><u>Exhibit M</u>: Affidavit of Dr. William T. Abraham sworn March 8, 2002, pp. 1334-1382, further including: <u>Exhibit A</u>: Curriculum vitae, pp. 1383-1428; <u>Exhibit B</u>: Notice of Allegation (pp. 3-19), pp. 1429-1449; <u>Exhibit C</u>: Canadian Letters Patent No. 2,212,548, pp. 1450-1481; <u>Exhibit D</u>: Glossary of medical terms, pp. 1482-1488, <u>Exhibit E</u>: Further commentary on prior art, pp. 1489-1506;</p> <p><u>Exhibit N</u>: Transcript of cross-examination of Dr. Abraham taken on November 26, 2002, pp. 1507-1628, further including: <u>Exhibit 1</u>: Abraham et al., 39 Advances in Internal Medicine, 22-47 (1994); <u>Exhibit 2</u>: Results of CONSENSUS Trial, 316 N.E.J. Med. 1429-1435 (1987); <u>Exhibit 3</u>: Bristow et al., 94 Circulation, 2807-16 (1996); <u>Exhibit 4</u>: Shakar et al., 31 JACC 1336-1340 (1998), <u>Exhibit 5</u>: Gilbert et al., 94 Circulation 2817-25 (1996); <u>Exhibit 6</u>: Abraham et al., 22 Hepatology, 737-743 (1995).</p> |
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| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br>(Use as many sheets as necessary) |    |    |    | <b>Complete if Known</b> |                     |
|   |    |    |    | Application Number       | 10/721,022          |
|   |    |    |    | Filing Date              | November 25, 2003   |
|   |    |    |    | First Named Inventor     | Lukas-Laskey et al. |
|   |    |    |    | Art Unit                 | 1614                |
|   |    |    |    | Examiner Name            | Not Yet Assigned    |
| Sheet   | 21 | of | 24 | Attorney Docket Number   | 04012.0384-00000    |

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| 129. | <p>Applicants' Record, Volume 4 of 7, filed in Hoffmann-La Roche Limited, and Smithkline Beecham Corporation v. The Minister of Health, and Novopharm Limited, Court No. T-84-02, containing an Index and:</p> <p><u>Exhibit O</u>: Affidavit of Dr. Nadia S. Giannetti sworn March 8, 2002, pp. 1629-1656, further including <u>Exhibit 1</u>: <i>Curriculum vitae</i>, pp. 1657-1669; <u>Exhibit 2</u>: Novopharm Notice of Allegation (Nov. 28, 2001), pp. 1670-1690; <u>Exhibit 3</u>: Canadian Letters Patent No. 2,212,548, pp. 1691-1723; <u>Exhibit 4</u>: List of prior art referenced in Notice of Allegation, pp. 1724-1737; <u>Exhibit 5</u>: Correspondence from Heenan Blaikie to Ogilvy Renault dated February 18, 2002, pp. 1739-1742;</p> <p><u>Exhibit P</u>: Transcript of cross-examination of Dr. Giannetti taken on December 20, 2002, pp. 1743-1842, further including <u>Exhibit 1</u>: Johnstone et al., 10 Can. J. Cardiol 613-631 (1994); <u>Exhibit 2</u>: Giannetti et al., 107 Am. J. Med., 228-233 (1999); <u>Exhibit 3</u>: Cecere et al., Can J Cardiol, Vol. 17, Supp C, Abstract 272 (Sept. 2001); <u>Exhibit 4</u>: Cecere et al., Can J Cardiol, Vol. 17, Supp C, Abstract 376 (Sept. 2001); <u>Exhibit 5</u>: Cantarovich et al., J. Heart Lung Trans, Vol 20(2), Abstract 246 (2001); <u>Exhibit 6</u>: Cantarovich et al., J. Heart Lung Trans, Vol 20(2), Abstract 166 (2001);</p> <p><u>Exhibit Q</u>: Affidavit of Dr. Mark Lautens sworn March 8, 2002, pp. 1843-1847, further including <u>Exhibit A</u>: <i>Curriculum vitae</i>, pp. 1848-1877; <u>Exhibit B</u>: Novopharm Notice of Allegation (Nov. 28, 2001), pp. 1878-1898; <u>Exhibit C</u>: Canadian Letters Patent No. 1,259,071, pp. 1899-1941;</p> <p><u>Exhibit R</u>: Affidavit of Edwin Gale sworn March 8, 2002, pp. 1942-1951, further including: <u>Exhibit A</u>: Copy of Canadian Letters Patent No. 2,212,548, pp. 1952-1983; <u>Exhibit B</u>: Novopharm Notice of Allegation (Nov. 28, 2001), pp. 1984-2004; <u>Exhibit C</u>: Chart illustrating various claim types used to cover pharmaceuticals, pp. 2005-2006; <u>Exhibit D</u>: Practice Notice regarding Chemical Patent Practice taken from the Canadian Patent Office Record of May 9, 1989, pp. 2007-2008; <u>Exhibit E</u>: Section 11.10.02 entitled "Method of Use and Use Claims" from the Canadian Manual of Patent Office Practice, pp. 2009-2013; <u>Exhibit F</u>: Canadian Letters Patent No. 2,212,548 claims grouped by type, pp. 2014-2015.</p> |
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|   |    |    |    | Application Number       | 10/721,022          |
|   |    |    |    | Filing Date              | November 25, 2003   |
|   |    |    |    | First Named Inventor     | Lukas-Laskey et al. |
|   |    |    |    | Art Unit                 | 1614                |
|   |    |    |    | Examiner Name            | Not Yet Assigned    |
| Sheet   | 22 | of | 24 | Attorney Docket Number   | 04012.0384-00000    |

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| 130. | <p>Applicants' Record, Volume 5 of 7, filed in Hoffmann-La Roche Limited, and Smithkline Beecham Corporation v. The Minister of Health, and Novopharm Limited, Court No. T-84-02, containing an Index and:</p> <p><u>Exhibit S</u>: Affidavit of Dr. John Parker sworn March 11, 2002, pp. 2016-2054, further including: <u>Exhibit A</u>: Curriculum vitae, pp. 2055-2077; <u>Exhibit B</u>: Notice of Allegation, pp. 2078-2098; <u>Exhibit C</u>: Canadian Letters Patent No. 2,212,548, pp. 2099-2130; <u>Exhibit D</u>: Glossary of medical terms, pp. 2131-2137; <u>Exhibit E</u>: Parker et al., 334 N.E.J. Med. 1349-1355 (1996), pp. 2138-2145; <u>Exhibit F</u>: Results of the Metoprolol in Dilated Cardiomyopathy (MDC) Trial 342 Lancet 1441-1446 (1993), pp. 2146-2152; <u>Exhibit G</u>: Results of CIBIS I Trial 90 Circulation, 1765-1773 (1994), pp. 2153-2162; <u>Exhibit H</u>: Pfeffer editorial on U.S. Carvedilol Trials, 334 N.E.J. Med. 1396-1397 (1996), pp. 2163-2165; <u>Exhibit I</u>: Results of COPERNICUS Trial, 344 N.E.J. Med. 1651-1658 (2001), pp. 2166-2174; <u>Exhibit J</u>: Results of BEST Trial, 334 N.E.J. Med. 1659-1667 (2001), pp. 2175-2184; <u>Exhibit K</u>: Further commentary on prior art, pp. 2185-2196; <u>Exhibit T</u>: Transcript of cross-examination of Dr. Parker taken on December 18, 2002, pp. 2197-2364, further including <u>Exhibit 1</u>: Johnstone et al., 10 Can. J. Cardiol 613-631 (1994); <u>Exhibit 2</u>: Parker, 19 Eur. Heart J. Suppl. I 115-119 (1998); <u>Exhibit 3</u>: Rapaport et al., 101 Am. J. Med. 4A-61S-4A70S (1996); <u>Exhibit 4</u>: Al-Hesayen et al., 39 JACC 1269-1274 (2002); <u>Exhibit 5</u>: Azevedo et al., Circulation 2053-2056 (2000); <u>Exhibit 6</u>: Parker et al., 84 Circulation 1040-1048 (1991); <u>Exhibit 7</u>: Azevedo et al., 33 JACC 186-191 (1999); <u>Exhibit 8</u>: Azevedo et al., Circulation 274-279 (1999); <u>Exhibit U</u>: Affidavit of Dr. Ian Winterborn sworn March 11, 2002, pp. 2365-2380, further including: <u>Exhibit A</u>: Curriculum vitae, pp. 2381-2385; <u>Exhibit B</u>: Notice of Allegation (Nov. 28, 2001), pp. 2386-2406; <u>Exhibit C</u>: Notice of Application, pp. 2407-2423; <u>Exhibit D</u>: Canadian Letters Patent No. 2,212,548, pp. 2424-2455; <u>Exhibit E</u>: Canadian Letters Patent No. 1,259,071, pp. 2456-2498; <u>Exhibit F</u>: Canadian Letters Patent No. 1,129,416, pp. 2499-2548; <u>Exhibit G</u>: United States Letters Patent No. 4,503,067, pp. 2549-2559.</p> |
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|   |    |    |    | Application Number       | 10/721,022          |
|   |    |    |    | Filing Date              | November 25, 2003   |
|   |    |    |    | First Named Inventor     | Lukas-Laskey et al. |
|   |    |    |    | Art Unit                 | 1614                |
|   |    |    |    | Examiner Name            | Not Yet Assigned    |
| Sheet   | 23 | of | 24 | Attorney Docket Number   | 04012.0384-00000    |

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| 131. | <p>Applicants' Record, Volume 6 of 7, filed in Hoffmann-La Roche Limited, and Smithkline Beecham Corporation v. The Minister of Health, and Novopharm Limited, Court No. T-84-02, containing an Index and:</p> <p><u>Exhibit V</u>: Affidavit of Dr. Mitchell Arnold Henry Levine sworn August 15, 2002, pp. 2560-2583, further including: <u>Exhibit A</u>: <i>Curriculum vitae</i>, pp. 2584-2614;</p> <p><u>Exhibit W</u>: Transcript of cross-examination of Dr. Mitchell Arnold Henry Levine taken on November 29, 2002, pp. 2615-2673, further including <u>Exhibit A</u>: Book entitled "Drugs of Choice: A Formulary for General Practice" (Canadian Medical Association: Toronto, 1995), pp. 2674-2849;</p> <p><u>Exhibit X</u>: Affidavit of Dr. Michael Bohm sworn August 16, 2002, pp. 2850-2875, further including <u>Exhibit A</u>: <i>Curriculum vitae</i>, pp. 2876-2980;</p> <p><u>Exhibit Y</u>: Transcript of cross-examination of Dr. Michael Bohm taken on December 9, 2002, pp. 2981-3028, further including: Exhibit 1: Article entitled "Different Intrinsic Activities of Bucidolol, Carvedilol and Metoprolol in Human Failing Myocardium," British Journal of Pharmacology (2000), 130, 1131-1139, pp. 3029-3037; Exhibit 2: Article entitled "Prospective Crossover Comparison of Carvedilol and Metoprolol in Patients with Chronic Heart Failure," American College of Cardiology, 38(4), 934-46 (2001), pp. 3038-3045; Exhibit 3: "β-Blocker Treatment of Chronic Heart Failure with Special Regard to Carvedilol" from book entitled "Heart Rate is a Determinant of Cardiac Function - Basic Mechanism and Clinical Significance," G. Hasenfuss et al. ed. (Steinkopff Verlag Darmstadt 2000) pp. 3046-3067.</p> <p><u>Exhibit Z</u>: Affidavit of Dr. Robert Rangno sworn August 20, 2002, pp. 3068-3094, further including <u>Exhibit A</u>: <i>Curriculum vitae</i>, pp. 3095-3102.</p> <p><u>Exhibit AA</u>: Transcript of cross-examination of Dr. Rangno taken on November 15, 2002, pp. 3103-3152.</p> |
| 132. | <p>Affidavit of Dr. Mark Lautens filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health, and Apotex Inc., Court No. T-149-02, further including:</p> <p><u>Exhibit A</u>: <i>Curriculum vitae</i>;</p> <p><u>Exhibit B</u>: December 12, 2001 Notice of Allegation from Apotex Inc. to Smithkline Beecham Pharma Inc.;</p> <p><u>Exhibit C</u>: Canadian Letters Patent No. 1,259,071;</p>  |
| 133. | <p>Notice of Application filed in GlaxoSmithKline Inc., and Smithkline Beecham Corporation v. The Minister of Health, and Apotex Inc., Court No. T-149-02.</p>   |
| 134. | <p>Record of the Respondent, Apotex Inc., filed in GlaxoSmithKline Inc. and Smithkline Beecham Corporation v. The Minister of Health and Apotex Inc., Court File No. T-149-02, further including:</p> <p>Exhibit 1: Memorandum of Fact and Law of the Respondent, Apotex Inc.</p>  |

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| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><i>(Use as many sheets as necessary)</i> |    |    |    | <b>Complete if Known</b>      |                     |
|  |    |    |    | <i>Application Number</i>     | 10/721,022          |
|  |    |    |    | <i>Filing Date</i>            | November 25, 2003   |
|  |    |    |    | <i>First Named Inventor</i>   | Lukas-Laskey et al. |
|  |    |    |    | <i>Art Unit</i>               | 1614                |
|  |    |    |    | <i>Examiner Name</i>          | Not Yet Assigned    |
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|  | 135. | Reasons for Order and Order, filed in GlaxoSmithKline Inc. and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court No. T-1871-01.         |  |
|  | 136. | Amended Reasons for Order and Order, filed in GlaxoSmithKline Inc. and Smithkline Beecham Corporation v. The Minister of Health and Pharmascience Inc., Court No. T-1871-01. |  |

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